

## REMARKS

This Response is submitted in reply to the final Office Action dated January 24, 2008 and the subsequently issued Advisory Action dated April 24, 2008. Both a Request for One-Month Extension and a Request for Continued Examination are submitted herewith with associated fees. The Commissioner is hereby authorized to charge any other fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 115808-504 on the account statement.

Claims 1-14 are pending. Claim 2 was previously canceled. Claims 1 and 3-14 are rejected under 35 U.S.C. §103. In response, Claims 1 and 11 have been amended. The amendments do not add new matter and are supported in the specification at page 8, lines 24-27. In view of the amendments and for the reasons set forth below, Applicants respectfully request that the rejection be withdrawn.

In the Office Action, Claims 1 and 3-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,888,171 to Okonogi et al. ("*Okonogi*") in view of EP 0298605 to Klapwijk et al. ("*Klapwijk*") and WO 99/48372 to Van Lengerich ("*Van Lengerich*"). Independent Claim 1 recites, in relevant part, a pellet comprising a compacted inner matrix and at least one coating, wherein the inner matrix comprises  $10^5$  to  $10^8$  viable micro-organisms per gram of pellet. Independent Claim 11 recites, in relevant part, a process for obtaining pellets to supplement a food product with  $10^5$  to  $10^8$  viable micro-organisms per gram of pellet. Applicants respectfully submit that the combination of cited references fail to disclose or suggest every element of the present claims. Moreover, Applicants submit that the cited references are not properly combinable.

*Okonogi* fails to disclose or suggest a pellet comprising  $10^5$  to  $10^8$  viable micro-organisms per gram of pellet as required, in part, by the present claims. Instead, *Okonogi* teaches granular products having viable microorganism levels above the range of the present claims. Specifically, Examples 1-3 in *Okonogi* teach viable microorganism counts (cfu) of  $59 \times 10^8$  ( $5.9 \times 10^9$ ),  $48 \times 10^8$  ( $4.8 \times 10^9$ ) and  $14 \times 10^8$  ( $1.4 \times 10^9$ ) per gram. See, *Okonogi*, column 8, line 5 to column 9, line 14. Applicants also submit that secondary references *Klapwijk* and *Van Lengerich* fail to remedy the above deficiency in *Okonogi*.

Similar to *Okonogi*, *Klapwijk* teaches viable microorganism levels above the range of the present claims. For example, *Klapwijk* teaches viable microorganism levels of  $1 \times 10^9$  to  $2 \times 10^{11}$  per gram. See, *Klapwijk*, page 3, lines 36-39. *Klapwijk* also teaches that the inoculum containing the *Lactobacillus* strain should have a viable count of at least  $10^9$  per gram, preferably above  $10^{10}$  per gram. See, *Klapwijk*, page 4, lines 7-8. Moreover, Example 3 in *Klapwijk* discloses viable count ranges of  $2.3$  to  $3.0 \times 10^{11}$ ,  $1.3$  to  $3.0 \times 10^{11}$ ,  $4.5$  to  $13.0 \times 10^9$  and  $2.5$  to  $28.0 \times 10^9$  per gram. See, *Klapwijk*, page 6, lines 12-16. As a result, *Klapwijk* fails to disclose or suggest any pellets comprising  $10^5$  to  $10^8$  viable micro-organisms per gram of pellet as required, in part, by the present claims.

Finally, like *Okonogi* and *Klapwijk*, *Van Lengerich* also fails to disclose or suggest any pellets comprising  $10^5$  to  $10^8$  viable micro-organisms per gram of pellet as required, in part, by the present claims. In fact, *Van Lengerich* fails to disclose or even suggest any viable microorganism levels for its edible composition or associated encapsulated component. Therefore, the combination of *Okonogi*, *Klapwijk* and *Van Lengerich* is deficient with respect to the present claims.

One of the advantages of the present claims is that by providing a pellet composition with the inner matrix characteristics as claimed, Applicants have greater flexibility in adding further functional components to the inner matrix. These further components include, for example, carrier materials or protective agents for the viable microorganisms, substances with high hygrocapacity, such as polymeric carbohydrates, and substances that promote compaction of the inner matrix, such as suitable binders and/or plasticizers. These further components can provide greater stability to the microorganisms, greater ability to retard water activity, and greater ability to support compaction. See, specification, page 11, lines 16-37. Example 2 in the specification illustrates the advantages of this flexibility by comparing Applicants' pellet compositions to a micro-encapsulated composition having microorganisms at a level above that of the present claims ( $5 \times 10^{10}$  cfu/gram). When compared to the micro-encapsulated composition, Applicants' pellet compositions displayed a prominently slower decrease in microorganism recovery, which illustrates a greater resistance to moisture absorption and resulting increased water activity. See, specification, page 22, lines 5-30.

Further, Applicants respectfully submit that the cited references are not properly combinable because the references are directed to completely different inventions. On one hand, *Okonogi* and *Van Lengerich* are directed to pelletized compositions. See, *Okonogi*, column 3, lines 9-23 and *Van Lengerich*, page 32, lines 11-13. By contrast, *Klapwijk* is not directed to pelletized compositions.

*Klapwijk*, as stated above, is directed to preparing bacterial compositions used in bread making. See, *Klapwijk*, page 1, lines 1-3. The examples disclosed in *Klapwijk* clearly only teach processes for preparing cell concentrate mixtures or processes for incorporating these mixtures into bread dough. See, *Klapwijk*, Examples 1-7. Though the final Office Action asserted that *Klapwijk* is not limited to breadmaking, the Advisory Action admits that *Klapwijk* does not teach a compaction process or compositions capable of being compacted into pellets. See, Advisory Action, page 3.

Applicants recognize that a need exists for a delivery system for probiotics, which provides a still prolonged life span of the probiotics in a liquid, moist or semi-moist environment. In particular, Applicants recognize the need to provide stable probiotics or a probiotics delivery system that can be added to a food product having an Aw (water activity) value above optimal for probiotics to survive. See, specification, page 3, lines 1-10. Applicants found surprisingly that by compacting dried micro-organisms together with a matrix, which may consist of dried food material, and by coating the pellets with a food-grade moisture barrier, Applicants could obtain an excellent stability over storage time. See, specification, page 3, lines 14-17.

Since incorporating probiotics into pellets, therefore, provides clear advantages over other product forms, one would have no reason to combine *Okonogi* and *Van Lengerich* (pelletized compositions) with *Klapwijk* (non-pellet compositions) to arrive at the present claims.

Therefore, Applicants respectfully submit that the combination of cited art fails to disclose or suggest every element of the present claims. Moreover, Applicants submit that the cited references are not properly combinable.

Accordingly, Applicants respectfully request that the obviousness rejection in view of *Okonogi*, *Klapwijk* and *Van Lengerich* be withdrawn.

For the foregoing reasons, Applications respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLP

BY 

Robert M. Barrett

Reg. No. 30,142

Customer No. 29157

Dated: May 21, 2008